UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,844	08/24/2006	Thomas W. Hodge	6395-68026-07	8385

46135 7590 08/20/2009

KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
08/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,844	HODGE ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,41,48,60 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,41,48,60 and 61* is/are rejected.

7)☒ Claim(s) *40,41,48,60 and 61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *August 24, 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election, without traverse, of HIV-1 in their response of June 29, 2009 is acknowledged. The elected invention is directed to a cellular method for identifying an agent that decreases pathogenicity of HIV-1 by decreasing Rab11A activity.

It is acknowledged that with Applicants' response of April 10, 2009, Claims 1, 3, 4, 6, 8, 18, 20-26, 29-32, 34-39, 43-45, and 47-59 are cancelled, Claims 40, 41, and 48 are amended, and Claims 60 and 61 are added. Claims 40, 41, 48, 60, and 61 are pending and are hereby examined.

Drawings-Objections

Objection to Figure 3A, for disclosing a sequence that is not identified by a sequence identifier number (SEQ ID NO:), is maintained.

Specification-Objections

The specification is objected to because the amendment to page 23, lines 1-6, makes no sense for the following reasons. (i) The phrase to be incorporated into page 23, lines 1-6, "sequence as follows contains a region that shares 75 percent sequence identity to that identified sequence (for example, 15+20* 100=75)." is identical to the preceding phrase on page 22. (ii) Said phrase to be incorporated into page 23, lines 1-6 (see above in (i)) appears to indicate that an alignment will follow. However, the amendment appears to indicate that the alignment is to be deleted. Clarification is required. As stated in the prior action, the sequence rules embrace all nucleotide sequences with ten or more bases. Such sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02).

Claims-Objections

Claims 40, 41, 48, 60, and 61 are objected to for encompassing non-elected subject matter.

Claim 61 is objected to for "gene product in a cell", which should be corrected to "gene product is in a cell".

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 41, 48, 60, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 40, the phrase "Rab11A enzymatic activity" renders the claim indefinite. It is unclear whether said phrase means measuring "Rab11A GTPase activity" or measuring some other downstream effect of "Rab11A GTPase activity". The skilled artisan would not know the metes and bounds of the recited invention. Claims 41, 48, 60, and 61, as dependent from Claim 40, are indefinite for the same reason. The specification fails to disclose detecting Rab11A GTPase activity per se but does disclose measuring vesicle transport from the trans-Golgi to the cell membrane as a means for detecting the downstream effect of Rab11A GTPase activity (PGPub [0231]). For purposes of examination, it is assumed that "Rab11A enzymatic activity" means measuring vesicle transport from the trans-Golgi to the cell membrane as a means for detecting the downstream effect of Rab11A GTPase activity.

For Claim 48, the term "retrovirus comprises…" renders the claim indefinite. It is unclear whether said term means, for example: (i) the retrovirus is a virus that comprises HIV-1 and other components or (ii) the retrovirus is HIV-1. The skilled artisan would not know the metes and bounds of the recited invention. Claim 60, as dependent from Claim 48, is indefinite for the same reason. For purposes of examination, it is assumed that "retrovirus comprises…" means the retrovirus is HIV-1….

Any subsequent rejection based, on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 40, 41, and 48 under 35 U.S.C. 112, first paragraph, for reasons explained in the prior action, is maintained. The specification, while being enablingfor a method of reducing the levels of the HIV protein p24 in HIV-infected JC53-BL cells using a pool of Rab11A siRNA oligonucleotides (Example 2; Fig 2), does not reasonably provide enablement for any biochemical, cellular, or in vivo method for identifying an agent that decreases pathogenicity of any retrovirus, wherein the method measures a decrease in Rab11A enzymatic activity. Claims 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The claims as amended herein are not directed to any pathogen, but to a retrovirus.

(B) The Office has failed to appreciate a primary purpose of the screening claims, which is to identify new properties of compounds. If one were to be required to know that a compound prior to screening possessed a certain property, such as altering pathogenicity of a pathogen via Rabl 1A (as the Office is currently requiring), then there would be no reason to perform the screening assay because such property had already been identified.

(C) Applicants also remind the Office of MPEP 2164.02, which states "...because only an enabling disclosure is required, applicant need not describe all actual embodiments."

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that the claims are so amended. However, the genus of all retroviruses is a large and variable genus. Clearly the specification has not enabled the skilled artisan to make and use a method for identifying agents that decrease pathogenicity of all retroviruses by measuring Rab11A activity. The skilled artisan would believe that, more likely than not, not all retroviruses are regulated by Rab11A.

(B) Reply: Applicants have failed to understand the Office's argument. The prior Action did not state that the specification must disclose if a compound, prior to screening, possessed a certain property, such as altering pathogenicity of a pathogen via Rab11A. The prior Action stated:

> "Without knowing whether a particular pathogen acts via Rab11A, any result from measuring the effect of a test agent on Rab 11A enzymatic GTPase activity cannot predict an effect of the test agent on the pathogenicity of the pathogen. Furthermore, the identity of pathogens that act via Rab11A is not predictable. Thus, the artisan is reduced to trial and error testing of every possible pathogen for pathogenicity via Rab 11A."

For the recited method to be useful, the skilled artisan must know whether each retrovirus to be analyzed is dependent on Rab11A for pathogenicity. Neither the specification nor the prior art provide such knowledge. Thus, the skilled artisan is reduced to trial and error testing of all retroviruses to determine if pathogenicity is dependent on Rab11A prior to performing the recited screening method.

(C) Reply: It is acknowledged that Applicants are not required to teach all enabled embodiments. However, the specification teaches only the single method of reducing the levels of the HIV protein p24 in HIV-infected JC53-BL cells using a pool of Rab11A siRNA oligonucleotides. Said single example is not sufficient to enable the skilled artisan to make and use any method of identifying an agent that decreases pathogenicity of any retrovirus, wherein the method measures a decrease in Rab11A enzymatic activity, wherein the method is an in vitro/biochemical method, a cellular method, or an in vivo method that uses any steps and reagents.

For these reasons and those explained in the prior actions, Claims 40, 41, 48, 60, and 61 are rejected under 35 U.S.C. 112, first paragraph/enablement.

Written Description

Rejection of Claims 40, 41, and 48, under 35 U.S.C. 112, first paragraph/written description, for reasons explained in the prior action, is maintained. Claims 60 and 61 are herein rejected under 35 U.S.C. 112, first paragraph, for the same reasons. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The claims as amended herein are not directed to any pathogen, but to a retrovirus.

(B) The specification provides methods for identifying agents that alter the pathogenicity of a retrovirus by measuring Rab11A enzymatic activity, including page 39, line 17 - page 41, line 29; and Examples 10, 12, 13 (in particular, page 74, lines 29-36)

(C) The specification provides guidance as to what retroviruses are to be screened (see at least page 30, line 28 - page 31, line 6).

(D) As noted by the Office action (pg 9), enzymatic assays, such as GTPase enzymatic assays, are well known in the art.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that the claims are so amended. However, the genus of all retroviruses is a large and variable genus. Clearly the specification has not described possession of a method for identifying agents that decrease pathogenicity of all retroviruses by measuring Rab11A activity. The skilled artisan would believe that, more likely than not, not all retroviruses are regulated by Rab11A.

(B) Reply: Said pages describe measuring retrovirus infection (pg 39, parg3), correlating the amount of infections with the level of Rab11A (parg brdg pg 39-40), assessing the effects of inhibiting a modulator of Rab11A by analyzing cellular changes, including vesicle transport (pg 40, parg 2), and binding of pathogens to Rab11A (pg 40, parg 3 to pg 41, parg 3). Only assessing the effects of inhibiting a modulator of Rab11A by analyzing changes in vesicle transport (pg 40, parg 2) is relevant to the instant invention.

(C) Reply: The claims are not limited to the retroviruses listed in said pages. Moreover, the specification fails to teach that a method for identifying an inhibitor of Rab11A is a method for identifying an agent that reduces the pathogenicity of all retroviruses listed in said

pages. The specification fails to describe a correlation between Rab11A activity and pathogenicity for all said retroviruses.

(D) Reply: It is acknowledged that GTPase enzymatic assays are known in the art. However, the specification fails to describe, or even allude to, use of a GTPase enzymatic assay as a means to measure Rab11A activity. The specification only describes use of analyzing changes in vesicle transport as a means to measure Rab11A activity (pg 40, parg 2).

For these reasons and those explained in the prior actions, Claims 40, 41, 48, 60, and 61 are rejected under 35 U.S.C. 112, first paragraph/written description.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652